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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,985	01/29/2004	Daniel Perreault	S63.2-11023-US01	5338
490 7590 06/06/2007 VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			EXAMINER COZART, JERMIE E	
			ART UNIT 3726	PAPER NUMBER
			MAIL DATE 06/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,985

Applicant(s)

PERREAULT ET AL.

Examiner

Jermie Cozart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-14,16,18-43 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-14 and 25-43 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,9,16,18,20 and 49 is/are rejected.
- 7) ☒ Claim(s) 7,8,10,11,19 and 21-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 4 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Kliefoth (1,968,456).

Regarding **claim 4**, Kliefoth discloses an apparatus (3) an introducer shaft having an internal lumen (Fig. 2).

Regarding **claim 49**, Kliefoth discloses the introducer shaft having an outer triangular configuration (Fig. 2).

Note that the limitations "for loading a medical device into a catheter delivery system", "constructed and arranged to matingly engage a crimping apparatus having a crimping chamber for reducing the diameter of said medical device from a first diameter to a second diameter prior to loading said medical device into said catheter delivery system", "for receiving a catheter delivery system", and "the mating engagement between said apparatus and said crimping apparatus provides for coaxial self-alignment between said internal lumen and said crimping chamber" are recitations of the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

3. Claims 1, 3, 4, 6, 9, 16, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Penner et al. (5,725,519).

Regarding **claim 1**, Penner discloses a loading apparatus (16, 64) for loading a self-expanding stent onto a balloon catheter delivery system in combination with a crimping apparatus (14) for reducing the diameter of the self-expanding stent from a first diameter to a second diameter prior to loading the self-expanding stem into the catheter delivery system, the loading apparatus (16, 64) having an alignment plug (16) with a tapered portion for matingly engaging (i.e. the loading and crimping intimately contact one another during the crimping/loading, figs. 1-2) a tapered portion of actuation hub (16) of the crimping apparatus.

Regarding **claim 3**, Penner discloses the mating engagement of the tapered portions provides for coaxial self-alignment between a lumen (64) of the loading apparatus and a crimping member (i.e. opening which receives lumen 64) of the crimping apparatus (14).

Regarding **claim 4**, Penner discloses an apparatus (16, 64) for loading a medical device into a catheter delivery system, the apparatus constructed and arranged to matingly engage (i.e. the loading and crimping intimately contact one another during the crimping/loading, figs. 1-2) a crimping apparatus (14) of the crimping apparatus having a crimping chamber (20, 30) for reducing the diameter of the medical device from a first diameter to a second diameter prior to loading the medical device into the catheter

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delivery system, the apparatus (16, 64) comprising an introducer shaft (64) having an internal lumen for receiving the catheter delivery system, wherein the mating engagement between the apparatus and the crimping apparatus provides for coaxial self-alignment between the internal lumen and the crimping chamber (20, 30).

Regarding **claim 9**, Penner discloses introducer plug (16) being modular with the introducer shaft (64).

Regarding **claim 16**, Penner discloses in combination, a crimping apparatus (14) for reducing the diameter of a medical device from a first diameter to a second diameter and a loading apparatus (16, 64), the crimping apparatus comprising a tapered portion constructed and arranged to matingly engage a complementary tapered portion of the loading apparatus (16, 64).

Regarding **claim 18**, the loading apparatus comprises an introducer shaft (64).

Regarding **claim 20**, the introducer shaft (64) has an introducer plug (16).

Note that the limitation "for introducing said medical device into a catheter delivery system" is a recitation of the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Note that the limitation "for loading a self-expanding stent into a catheter,"
"constructed and arranged to matingly engage a crimping apparatus for reducing the diameter of the self-expanding stent from a first diameter to a second diameter prior to

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loading the self-expanding stem into the catheter delivery system," "for matingly engaging the crimping apparatus" are recitations of the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

See column 5, line 15 – column 7, line 49, and figures 2-5 for further clarification.

Allowable Subject Matter

4. Claims 7, 8, 10, 11, 19, and 21-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Claims 12-14 and 25-43 are allowed.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 4, 16, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 29, 2007


JERMIE E. COZART
PRIMARY EXAMINER